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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,350	12/07/2000	Allan Svendsen	5200.220-US	1715
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NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110				
			EXAMINER KERR, KATHLEEN M	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/732,350	<b>Applicant(s)</b> SVENDSEN ET AL.	
	<b>Examiner</b> Kathleen M Kerr	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 64-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/032,315.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (mailed on August 22, 2003), Applicants filed response and amendment received on January 30, 2004. Said amendment amended Claim 64 and added new Claims 96-105. Thus, Claims 64-105 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for U.S. non-Provisional Application Nos. 09/036,260 (USPN 6,184,015) filed on September 15, 1999 and 09/032,315 (USPN 5,985,818) filed on February 27, 1998 as well as the foreign application 0222/97 filed in Denmark on February 28, 1997 as requested in the declaration.

### ***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

3. Previous rejection of Claims 64-95 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicant's amendment.

### ***Maintained - Claim Rejections - 35 U.S.C. § 112***

4. Previous rejection of Claims 64-95 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the structure of the claimed variants is inherent; the Examiner disagrees. While a specific enzyme structure has an inherent enzyme function based on that structure, a specific enzyme function may be accomplished by

any structure capable of performing that function and thus, having no specific or inherent structure. Applicants also argue that they should not be limited to specific “strains” [sic] (apparently meaning specific protein sequences) considering *In re* Goffe; the Examiner does not disagree and has not required that Applicants claim only point mutations. What is required is a structure, even a broad one, and function of the claimed material as in Claims 96-105.

***Maintained - Claim Rejections - 35 U.S.C. § 102***

5. Previous rejection of Claims 64 and 68 under 35 U.S.C. § 102(b) as being anticipated by Germann *et al.* is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive for the following reasons. The Examiner notes that Applicants describe this rejection as a rejection under 35 U.S.C. § 103; this is incorrect since the rejection is an anticipatory-type rejection under 35 U.S.C. § 102(b). Applicants argue that the protein of Germann *et al.* is not a variant since it is a wild-type protein. In rebuttal, the Examiner notes that the wild-type sequence of Germann *et al.* is identical to the variant sequence in the claim. As previously noted, “Germann *et al.* teach the amino acid sequence of laccase from *Neurospora crassa*. Said sequence, when aligned to SEQ ID NO:10 (see previously attached alignment), has the A108V mutation. Thus, the *N. crassa* sequence can be considered a mutant of SEQ ID NO:10 with numerous mutations, particularly the claimed mutation - A108V.” Whether the product of the claimed protein is obtained by mutation of SEQ ID NO:10 or from a wild-type source, the product is still the same and is within the scope of the claimed invention. The rejection is, thus, maintained.

## NEW ISSUES

### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 64-105 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 64 and 69 specify mutant N109D, which lacks support in the specification as originally filed (see pages 9 and 12 of the specification as well as original claim 15). Applicants are required to delete the new matter in response to this rejection or to point out specific support (page and line number) in the specification as originally filed.

7. Claims 64-105 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for variant laccases of specific structure, does not reasonably provide enablement for variant laccases having undefined or broadly defined structures. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in

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Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification describes the three-dimensional structure of laccase from *Coprinus cinereus*. The specification describes other laccases related as *Coprinus*-like laccases by sequence and homology to the *C. cinereus* sequence, some sequences having as little as about 57% homology with the *C. cinereus* laccase (see pages 4-7). While the instant specification points to sequence locations for mutations that might affect (1) oxidation potential, (2) pH optimum, (3) mediator efficiency, and (4)  $O_2/OH^-$  pathway based on the disclosed 3D structure (see pages 8-12), the overall structural requirements for proteins having laccase activity are not described. The specification presents no guidance or working examples in the production of laccase variants having mutations other than those specifically denoted on pages 8-12 wherein

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said mutants would retain their activity, i.e., their laccase-character. The nature of the invention is that the product is a large, functional protein and with such a great deviation from a sequence known to possess laccase activity, the predictability of functionality becomes extremely low. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

In particular for Claims 96-105, the Examiner notes that the parent claims require mutations relative to SEQ ID NO:10 (*Myceliophthora thermophila* laccase) but the overall structure must be similar to SEQ ID NO:1 (*Coprinus cinereus* laccase), which natively is only 56.5% homologous to SEQ ID NO:10 (see page 4).

#### ***Summary of Pending Issues***

8. The following is a summary of the issues pending in the instant application:
  - a) Claims 64-105 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
  - b) Claims 64-95 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
  - c) Claims 64-105 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
  - d) Claims 64 and 68 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Germann *et al.*

#### ***Allowable Subject Matter***

9. The Examiner notes that claims would be allowable when drawn to variants having the exact sequence of SEQ ID NO:10 with only particular mutations noted.

***Conclusion***

10. Claims 64-105 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **non-final** based on the new grounds of rejection set forth herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Examiner  
Art Unit 1652

April 6, 2004